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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,899	04/12/2001	Jean-Marc Balloul	032751-052	1686

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EXAMINER
BROWN, TIMOTHY M

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/832,899	BALLOUL ET AL.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7,16,17 and 19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 8-10* is/are rejected.

7)☐ Claim(s) *4-6,11-15 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *27 October 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

In their response received October 27, 2003, Applicants elected with traverse of Group I, claims 1-15 and 18. Applicants further elected the heterologous ligand moiety for tumor specific antigen (claim 5), wherein the heterologous ligand moiety is included in a poxviral chimeric protein (claim 8), and wherein the specific poxviral polypeptide is encoded by the A27L gene (claim 9).

Applicants traversed the restriction requirement arguing that rejoinder of inventions A-D would not place a serious burden on the Examiner since the claims would "substantially overlap." The Examiner agrees and Inventions A-D have been rejoined. However, the restriction between groups, and the restriction between SM3 monoclonal antibody fragment (claim 7) and the polypeptide comprising a chimeric protein (claim 8) is maintained. Thus, claims 7, 16, 17 and 19-23 are withdrawn from consideration.

Contrary to Applicants' argument, Groups I-IV do not derive overlapping searches by depending from claim 1. A search of claim 1, which is drawn to a poxvirus particle, would not entail searching for a method for poxvirus treatment (Group III), or a method for purifying poxvirus particles (Group IV). Consequently, Groups I-IV do not involve overlapping searches.

Claim Objections

Claim 1 is objected to for failing to define the first occurrence of "EEV." Claim 4 is similarly objected to for failing to define "IMV." Correction in accordance with the specification is required.

Claims 4-6, 11-15 and 18 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 4-6 and 11-15 not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

Courts weigh a number of factors when determining whether undue experimentation exists. These factors include: breadth of the claims; the state of the prior art; the level of predicatability in the art; the existence of working examples; and the quantity of experimentation that is needed to make and use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Claims 9 and 10 are drawn to a poxviral particle having targeted infection specificity, wherein the targeting ligand is fused to the A27L gene product (p14). Experiments with p14-

deficient vaccinia demonstrate that p14 is critical to vaccinia's ability to infect host organisms.[1] Thus, fusing a targeting ligand to p14 would interfere with vaccinia's ability to infect host organisms thereby making the inventive poxviral particle inoperative. Furthermore, Applicants have not provided any working examples to show that modifying p14 in the claimed manner would produce a poxviral particle capable of targeting specific cells. Therefore, the skilled artisan would have to perform undue experimentation in order to practice Applicants' invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 9 and 10 are drawn to a poxviral particle with targeting specificity wherein the targeting ligand is fused to p14. As noted above, Applicants fail to provide working examples that demonstrate a poxviral particle may retain its capacity to infect when the p14 protein is compromised by fusion to a targeting moiety. Accordingly, claims 9 and 10 fail the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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[1] Hsiao. J.C. "Cell Surface Proteoglycans Are Necessary for A27L Protein-Mediated Cell Fusion: Identification of the N-tmerinal Region of A27L Protein as the Glycoaminoglycan-Binding Domain" Journ. of Virol. (October 1998) 72, pp. 8374-8379

Claims 1-3 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Paul et al., (Paul. S. "Redirected cellular cytotoxicity by infection of effector cells with a recombinant vaccinia virus encoding a tumor-specific monoclonal antibody" 2000 Cancer Gene Ther. (2000) 7, pp. 615-623).

As understood by the Examiner, claims 1-3 are drawn to a poxviral particle having specificity to a target cell, the specificity being provided by a heterologous ligand, with the exception that when said poxviral particle is EEV, said ligand is not an antibody against ErbB-2. Paul et al. disclose the inventive poxviral particle. Paul et al. disclose a recombinant vaccinia vector encoding a monoclonal antibody directed against tumor antigen CO17-1A (abstract, lines 4-5). The tumor antigen is anchored by a poxviral transmembrane protein (Fig. 1) such that the tumor antigen targets the recombinant vaccinia virus to gastrointestinal carcinomas (abstract, line 6). The poxviral particle is derived from the Copenhagen vaccinia strain (p. 616).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Scholl S.M. "Recombinant Vaccinia Virus Encoding Human MUC1 and IL2 as Immunotherapy in Patients with Breast Cancer" Journ. of Virol. (2000) Vol. 23, pp. 570-580. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tmb

Patent Examiner, 1648